

Application Number 10/008,243
Amendment dated September 10, 2004
Responsive to Office Action of July 12, 2004

REMARKS

This amendment is responsive to the Office Action dated July 12, 2004. Applicants have amended claims 4, 17, 20, 28, 35, 41, 47, 52 and 53. Claims 1-5 and 7-59 are still pending.

The Finality of the current Office Action is improper and must be withdrawn

In the Office Action, the Examiner advanced at least one new rejection. This new rejection was not necessitated by a claim amendment submitted by Applicants. This new rejection was also not based on prior art submitted by Applicants in an IDS based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c). Accordingly, the Finality of the current Office Action is improper and must be withdrawn by the Examiner.

MPEP 706.07(a) sets forth the standard for when an Examiner can issue a Final rejection in a second Office Action. MPEP 706.07(a) provides that:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

In the instant case, the Examiner's rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Belt et al. (U.S. Patent 4,420,078) (hereafter Belt) is a new grounds of rejection.

Applicants' previous amendment to claim 1 did not necessitate this new grounds of rejection. To be sure, claim 1 was merely amended to include limitations that were previously recited in dependent claim 6, now canceled. Any amendment that introduces the limitations of a dependent claim into the independent claim cannot necessitate new grounds of rejection under MPEP 706.07(a). All of the features of independent claim 1 were originally presented in dependent claim 6, now canceled. The amendment to claim 1 did not change the scope of the claimed subject matter of previous claim 6, but simply introduced the dependent features of claim 6 into independent claim 1. For this reason, the amendment to claim 1 did not necessitate the new grounds of rejection.

The Belt reference was also not submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c). Therefore, the Examiner has not met either of

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the requirements of MPEP 706.07(a). The Finality of the current Office Action must be withdrawn.

Preliminary observations on the proceedings to date

Applicants respectfully believe that the Examiner is acting in violation of the Administrative Procedure Act. Applicants also believe that at least some of the Examiner's current rejections are so vague and lacking in rationale that the rejections violate the United States Constitutional requirements for procedural due process.

The Administrative Procedure Act, which governs the proceedings of agencies and related judicial review, establishes a scheme of "reasoned decision making." Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational.¹ This standard, as specifically interpreted in patent cases before the Patent and Trademark Office, requires that the agency not only have reached a sound decision, but have articulated the reasons for that decision.²

In the instant case, many of the rejections lack any rational or explanation. In particular, in many cases, the Examiner has failed to provide any explanation of how or why the Examiner feels that Applicants claims are rendered unpatentable by the applied references. Accordingly, Applicants are left to guess as to the Examiner's rationale for the rejections that do not provide any reasoned analysis of the similarities and/or differences between Applicants' claims and the applied prior art references.

Applicants further submit that some of the Examiner's rejections are so vague that they are unconstitutional as failing to provide Applicants with procedural due process.³ To the extent that the Examiner disagrees with any of the following arguments, Applicants specifically request that the Examiner articulate a reasoned rationale for any rejections that the Examiner asserts, as required by the Administrative Procedure Act and procedural due process requirements of the United States Constitution.

¹ See *Allentown Mack Sales and Service, Inc. v. National Labor Relations Bd.*, 522 U.S. 359, 374 (1998) (citations omitted)

² See *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

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Claim Rejections

In Applicants' latest response, Applicants provided a detailed analysis of each rejection, demonstrating how the applied prior art lacks features of various independent and dependent claims. Applicants believe that the Examiner failed to address Applicant's arguments. Applicants hereby incorporate all of those arguments of the previous response into this response. For purposes of brevity, however, Applicants' following remarks are focused solely on the independent claims. Applicants do not acquiesce to any of the Examiner's rejections of dependent claims or characterizations of the prior art, and specifically reserve the right to further address the dependent claims.

Claim 1

Independent claim 1 recites a device comprising a medical device, and a pouch comprising an anchor that fastens the pouch to the medical device, the pouch containing an electrode. In the Office Action, the Examiner rejected claim 1 under 35 U.S.C. §102(b) as being anticipated by Belt. The only rationale given by the Examiner in support of this rejection was a statement that Belt discloses an anchor comprising snap-fastener member 52 and a lip comprising flap panel 50.

Applicants traverse the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Belt. Belt fails to disclose or suggest, not one, but several features of claim 1. In particular, Belt clearly fails to disclose or suggest a pouch containing an electrode, as recited in claim 1. In addition, Belt also fails to disclose or suggest an anchor that fastens the pouch to the medical device, as recited in claim 1. For at least these reasons, the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Belt, should be withdrawn.

Belt is directed to a carrying case for a cardiac pacemaker. Nothing in Belt, however, suggests a pouch containing an electrode, as recited in claim 1. In fact, electrodes are neither illustrated or described anywhere in Belt. To be sure, the term "electrode" does not appear

³ As one example, claims 1-5, 10, 15, 16, 18-20, 29, 30, 53 and 55-59 were rejected under 35 U.S.C. §102(c) as being anticipated by Janac et al. (U.S. Patent 6,675,051). In this rejection, the Examiner failed to provide any rational or explanation, whatsoever, for the rejection.

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anywhere in Belt. As best as Applicants can discern, the cardiac pacemaker illustrated in Belt includes conductive leads 25, 26, which would have pacing electrodes disposed on their respective distal ends, and which would be implanted within a patient's heart. Belt fails to describe such electrodes, however, and clearly lacks any suggestion of a pouch that contains an electrode, as required by claim 1.

Belt also appears to lack any suggestion of a pouch, whatsoever, much less a pouch that contains an electrode, as required by claim 1. Again, Belt illustrates a carrying case for a cardiac pacemaker. As best as Applicants can discern, the Examiner appears to be construing this "carrying case" as a pouch.

However, the "carrying case" illustrated in Belt clearly does not contain an electrode, as required by claim 1. Moreover, the carrying case illustrated in Belt does not include an anchor that fastens a medical device to the pouch. The Examiner appears to be construing snap-fastener member 52 and flap panel 50 as an anchor. Elements 52 and 50, however, do not fasten a pouch to a medical device. Instead, elements 52 and 50 appear to form a lockable cover of a pacemaker carrying case. As shown in Belt, the pacemaker is held within the carrying case, and element 50 forms part of the carrying case and extends over the top of the pacemaker. Element 52 also forms part of the carrying case and mates with element 50.

Nothing in Belt is suggestive of a pouch that contains an electrode, or an anchor that fastens the pouch containing the electrode to a medical device. The rejections of claim 1 as being anticipated by Belt, and the rejections of the dependent claims of claim 1 should be withdrawn for at least these reasons.

In the Office Action, the Examiner also rejected independent claim 1 as being anticipated by Janae et al. (U.S. Patent 6,675,051) (hereafter Janae). The Examiner failed to provide any rational or explanation, whatsoever, for this rejection.

As a preliminary observation, Applicants note that Janae, unlike Belt, is at least somewhat similar to Applicants' claimed invention. However, Janae clearly lacks features recited in claim 1, specifically, the anchor that fastens the pouch containing the electrode to a medical device.

Janae describes and illustrates a conventional electrode package. The electrode package of Janae includes an interior for storing one or more electrodes and a window that provides a

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view into the interior. However, Janae appears to lack any suggestion of an anchor that fastens the package to a medial device. Furthermore, the Examiner has failed to identify anything in Janae that suggests an that fastens the package to a medial device. Accordingly, the Examiner has clearly failed to establish a prima facie case of anticipation. The rejection of claim 1 as being anticipated by Janae and the rejections of the dependent claims of claim 1 should be withdrawn for at least these reasons.

Claims 17, 28, and 53

Independent claim 17 recites a device comprising a pouch containing a defibrillation electrode, the pouch comprising a handle that when pulled causes the pouch to tear open. Claim 28 recites a method comprising sealing a defibrillation electrode in a pouch, and constructing a handle on the pouch that when pulled causes the pouch to tear open. These two claims have been amended to specifically recite that the handle when pulled causes the pouch to "tear" open. Claim 53 recites a method comprising obtaining a pouch containing a defibrillation electrode; and tearing open the pouch by pulling a handle.

In the Office Action, the Examiner rejected claims 17, 28 and 53 under 35 U.S.C. §102(b) as being anticipated by Walters et al. (U.S. Patent 6,048,640) (hereafter Walters). In support of this rejection, the Examiner stated that Walters show a part (end 14) that is designed especially to be grasped by a hand. Based on this observation, the Examiner appears to be concluding that Walters discloses a pouch having a handle that when pulled causes the pouch to tear open.

Applicants respectfully submit that the Examiner's interpretation of Walters as disclosing a handle is incorrect. Walters lacks any suggestion of a pouch having a handle. On the absolute contrary, the pouch of Walters lacks a handle. For this reason, a user is required to tear the pouch by ripping part 14 from the pouch. In contrast, the pouch recited in Applicants' claims 17 and 28 specifically requires a handle, and claim 53 specifically requires pulling on a handle.

The Examiner's interpretation of part 14 as being a handle is completely unreasonable. Applicants claims 17 and 28 requires a pouch comprising a handle. Walters shows a pouch without a handle. The Examiner's statement end 14 is designed especially to be grasped by a hand appears to have been made-up by the Examiner and is unsupported by the evidentiary record. Nothing in Walters indicates that end 14 is designed especially to be grasped by a hand.

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On the contrary, Walters specifically states that "the operator merely tears off the first end 14."⁴ The rejection of claims 17 and 28 as being anticipated by Walters should be withdrawn. The rejection of claim 53 as being anticipated by Walters should also be withdrawn.

In the Office Action, the Examiner also rejected claim 53 as being anticipated by Janae. However, Janae clearly lacks any suggestion of a handle that is pulled to tear open the pouch, as recited in claim 53, and the Examiner identified no such teaching in Janae. Withdrawal of this rejection is requested. Applicants also note that this rejection of claim 53 may have been an unintentional mistake by the Examiner, as Janae was not used in rejecting any other claims that recite a handle that tears open the pouch.

In the Office Action, the Examiner also rejected claims 17, 28 and 53 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay et al. (U.S. 5,951,598) (hereafter Bishay). Applicants respectfully observe that this rejection is inconsistent with the rejection of claims 17, 28 and 53 under 35 U.S.C. §102(b) as being anticipated by Walters. On one hand, the Examiner is stating that Walters discloses all of the elements of claim 17, 28 and 53, and on the other hand, the Examiner is stating that Walters lacks disclosure of one or more elements of claims 17, 28 and 53. Applicants' request clarification on the inconsistency of the Examiner's position.

In any case, Bishay lacks any teaching that would have led a person of ordinary skill in the art to modify the pouch of Walters to include a handle. To be sure, Bishay, like Walters lacks any suggestion of a handle that when pulled causes the pouch to tear open. For this reason, Applicants respectfully request withdrawal of the rejections of claims 17, 28 and 53 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay.

The Examiner also rejected claim 28 and 53 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova (U.S. Publication Number 2003/0114885) (hereafter Nova). Applicants reserve the right to challenge the prior art status of Nova or other references cited in the Office Action.

Applicants again note that the Examiner's rejections are inconsistent. On one hand, the Examiner is rejecting claims 28 and 53 as being unpatentable over Walters in view of Bishay,

⁴ See Walters column 4, line 21.

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implying that Walters and Bishay disclose all of the features of claims 28 and 53. On the other hand, the Examiner is rejecting claims 28 and 53 over Walters in view of Bishay and further in view of Nova, implying that Walters and Bishay lack one or more of the features of claims 28 and 53. Clarification of the Examiner's position is respectfully requested.

In any case, Nova provides no additional teaching that would have led a person of ordinary skill in the art to recognize the features of claims 28 and 53. In particular, Nova lacks any suggestion of a pouch, or a handle that when pulled causes the pouch to tear. Instead Nova teaches a outer shell 12 that defines a storage bay 20, and a releasable liner 46 that seals storage bay 20. While releasable liner 46 appears to include a handle, the package of Nova is not a pouch, and in any case, pulling on the handle releasable liner 46 simply removes the liner and does not cause anything to tear.

In the Office Action, the Examiner also rejected claims 17 and 28 under 35 U.S.C. §102(b) as being anticipated by Faller et al. (U.S. Patent 6,611,709) (hereafter Faller). For this rejection, the Examiner again failed to provide any rational, explanation or reasoning for the rejections, as required by law.

Faller fails to disclose or suggest the features of claims 17 and 28. In particular, Faller fails to disclose or suggest a handle that when pulled causes the pouch to tear open.

Faller describes an electrode package that includes a tab. The described tab, however, does not open the package, but is used to provide a safety seal and expiration date for the electrode. In particular, nothing in Faller suggests that when a user pulls on the tab, the electrode package is torn open. On the contrary, once the tab of Faller is broken, it appears that a user would still need to open the package in order to access the electrodes. Thus, the tab merely forms a safety seal, and may include an expiration date so that shelf life of the electrodes can be properly monitored. The rejections of claims 17 and 28 as being anticipated by Faller should be withdrawn.

In the Office Action, the Examiner also rejected claim 17 under 35 U.S.C. §103(a) as being unpatentable over Freeman et al. (U.S. Patent 5,462,157) (hereafter Freeman) in view of Jacobsson et al. (U.S. 4,986,465) (hereafter Jacobsson).

Freeman discloses an electrode package, but like the other applied reference, lack any suggestion of handle that when pulled causes a pouch to tear open, as recited in claim 17.

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Moreover, the package of Freeman is not even a pouch, but comprises a structurally rigid sheet with a liner that is adhesively secured to the sheet.⁵

In the Office Action, the Examiner stated that Freeman shows all of the claimed features except for a ring shaped handle, which is not recited in independent claims 17, but is recited, e.g., in dependent claim 21. The Examiner's position, therefore, seems to be inconsistent with regard to the features of independent claim 17. Applicants request clarification on this point.

Contrary to the Examiner's statement, however, Freeman does not teach all of the features of claims 17, 21 and 22 except for a ring shaped handle. In particular, Freeman lacks any suggestion of a pouch, but describes a structurally rigid sheet with a liner that is adhesively secured to the sheet. Also, Freeman lacks any suggestion of a handle that when pulled tears open a pouch. The electrode package of Freeman includes tabs that can be forced to break a heat seal and separate a sheet from a liner.

Jacobson lacks any teaching that would have led a person of ordinary skill in the art to modify the electrode package of Freeman to include a pouch with a handle that when pulled tears open the pouch. Furthermore, a person of ordinary skill in the art viewing Freeman would not have even looked to Jacobson for at least two reasons. First, Jacobson is totally unrelated to medical devices or electrode packaging. Instead, Jacobson is concerned with packaging of consumer goods, and is specifically concerned with providing an opening that improves pouring properties of a container. Accordingly, a person of ordinary skill in the art would not have looked to Jacobson for guidance in the field of medical devices and electrode packaging.

Second, Freeman purports to address the issue of electrode package opening through the use of tabs that can be forced to break a heat seal and separate a sheet from a liner to open the package of Freeman. Thus, having identified a solution to electrode packaging consistent with the teaching of Freeman, a person of ordinary skill in the art would have had no reason to look elsewhere, much less look to unrelated consumer packaging techniques for improved liquid pouring properties, as taught by Jacobson.

In short, Applicants submit that the prior art lacks any motivation that would have led a person of ordinary skill in the art to even look to Jacobson. Further, even if a skilled person

⁵ See column 3, lines 43-50

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became aware of Jacobson, there would have been no reason to modify the tabs of Freeman into a handle, as Freeman purports to solve problems related to opening of electrode packages. Finally, Jacobson describes consumer packaging techniques for improved liquid pouring properties, and appears to have no applicability to electrode packaging in the medical device field. For at least this reason, Applicants request withdrawal of the rejection of claim 17 as being unpatentable over Freeman in view of Jacobson.

As a final point on claims 17, 28 and 53, Applicants note that these claims recite very similar features. However, Applicants are very confused as to why the Examiner rejects all three of these claims together in some of the rejections, but then only rejects one or two of these claims in other rejections. The inconsistency of the Examiner's position is further obfuscating the issues at hand, and compounds the problems mentioned above, relating to the Examiner's lack of analysis or rational. Applicants are very confused as to the Examiner's position, which seems to change throughout the Office Action.

Claims 35 and 41

Independent claim 35 recites a device comprising a defibrillation electrode, a human figure printed on the defibrillation electrode, and an electrode symbol printed on the human figure. As claimed, the human figure is oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle, wherein the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy. Applicants have amended this claim to clarify that the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy.

Independent claim 41 recites a method comprising printing a human figure on a defibrillation electrode, and printing an electrode symbol on the human figure on the defibrillation electrode. As claimed, the human figure is oriented on the defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, the defibrillation electrode will be oriented at the angle, wherein the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy. Like claim 35, claim 41 has been amended to clarify

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that the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy.

Applicants traverse the rejections of independent claims 35 and 41 and submit that the applied references lack any suggestion of a human figure oriented on a defibrillation electrode at an angle so that when the defibrillation electrode is applied to a patient with the head of the patient and the head of the human figure in the same direction, wherein the angle defines proper placement of the defibrillation electrode on the patient for defibrillation therapy.

In the Office Action, the Examiner rejected claim 35 under 35 U.S.C. §102(e) as being anticipated by Nova. This rejection is without merit, particularly with respect to the amended claim 35. While Nova shows electrodes printed with human figures, the orientation of the human figures on the electrodes of Nova are not oriented at angles that define proper placement of the defibrillation electrodes when the head of the patient and the head of the human figure are in the same direction. As can be clearly seen in FIG. 8 of Nova, the heads of figures on electrodes 22 would not be oriented in the same direction as that of the patient, when the electrodes are placed for defibrillation therapy. Applicants' claimed invention simplifies proper placement of an electrode, relative to the teaching of Nova, by orienting the human figure on the electrode in a manner that defines proper placement of the defibrillation electrode when the head of the figures is oriented in the same direction as the head of the patient. This is quite simply not shown or suggested in Nova. Withdrawal of the rejection of claim 35 under 35 U.S.C. §102(e) as being anticipated by Nova is solicited.

In the Office Action, the Examiner also rejected claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay. In this rejection, the Examiner recognized that Walters fails to suggest instructive pictures on the electrodes, but stated that Bishay teaches the use of images on electrodes to assist an operator in determining placement of the electrodes.

Applicants respectfully traverse the rejections of claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay, particularly to the extent such rejections are deemed applicable to the amended claims. While Bishay shows electrodes printed with human figures, the orientation of the human figures on the electrodes of Bishay are not oriented at angles that define proper placement of the defibrillation electrodes when the head of

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the patient and the head of the human figure are in the same direction. In this sense, Bishay is very similar to Nova. As can be clearly seen in FIG. 1 of Bishay, the heads of figures on electrodes 12 and 12' would not be oriented in the same direction as that of the patient, when the electrodes are placed for defibrillation therapy.

Applicants' claimed invention simplifies proper placement of an electrode, relative to the teaching of Bishay, by orienting the human figure on the electrode in a manner that defines proper placement of the defibrillation electrode when the head of the figures is oriented in the same direction as the head of the patient. This is, quite simply, not shown or suggested in Bishay or any of the other applied references. Withdrawal of the rejections of claim 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay is solicited.

In the Office Action the Examiner also rejected claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova. Applicants note that this rejection is inconsistent with the rejection of claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay. On one hand, the Examiner is stating that that Walters and Bishay disclose all of the features of claims 35 and 41, and on the other hand, the Examiner is stating that Walters and Bishay fail to suggest at least one feature of claims 35 and 41. Clarification is requested on this inconsistency.

In any case, Applicants respectfully traverse the rejections of claims 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova, particularly to the extent such rejections are deemed applicable to the amended claims. As outlined above, neither Bishay nor Nova, nor any applied references suggests electrodes printed with human figures oriented at angles, wherein the angles define proper placement of the defibrillation electrodes for defibrillation therapy when the head of the patient and the head of the human figure are in the same direction.

While Bishay and Nova show electrodes printed with human figures, the orientation of the human figures on the electrodes of Bishay are not oriented at angles that define proper placement of the defibrillation electrodes when the head of the patient and the head of the human figure are in the same direction. Withdrawal of the rejections of claim 35 and 41 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay and further in view of Nova is solicited.

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Claim 47

Claim 47 recites a device comprising a right defibrillation electrode including a first instructive picture, and a left defibrillation electrode including a second instructive picture. As claimed, the first instructive picture includes a right electrode symbol on a first human figure, the first human figure oriented in a first direction relative to the right defibrillation electrode, and the second instructive picture includes a left electrode symbol on a second human figure, the second human figure oriented in a second direction relative to the left defibrillation electrode. Applicants have further amended claim 47 to specify that the first direction is different than the second direction.

In the Office Action, the Examiner rejected claim 47 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay. Applicants respectfully traverse the rejection of claim 47 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay, particularly to the extent such rejection is deemed applicable to the amended claim. As noted by the Examiner, Walters fails to suggest instructive pictures on the electrodes. However, the Examiner stated that Bishay teaches the use of images on electrodes to assist an operator in determining placement of the electrodes.

While Bishay shows electrodes printed with human figures, the orientation of the human figures on the electrodes of Bishay are the same for both electrodes, and not different, as recited in amended claim 47. For at least this reason, the rejection of claim 47 under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Bishay should be withdrawn.

CONCLUSION

All claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. Applicants do not acquiesce with any of the current rejections or the Examiner's characterizations of the prior art. Applicants also reserve the right to challenge the prior art status of one or more of the applied

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references.⁶ The Examiner is invited to telephone the below-signed attorney to discuss this application.

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⁶ As one example, Applicants may challenge the prior art status of Nova. Applicants have not yet determined whether the disclosure of Nova relied upon by the Examiner is supported by the provisional application priority claim in Nova.